



Standard Specification for Calcium Phosphate Coatings for Implantable Materials¹

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1. Scope

1.1 This specification covers the material requirements for calcium phosphate coatings for surgical implant applications.

1.2 In particulate and monolithic form, the calcium phosphate materials system has been well-characterized regarding biological response (1,2)² and laboratory characterization (2-4). Several publications (5-10) have documented the *in vitro* and *in vivo* properties of selected calcium phosphate coating systems.

1.3 This specification includes hydroxylapatite coatings, tricalcium phosphate coatings, or combinations thereof, with or without intentional minor additions of other ceramic or metallic,³ and applied by methods including, but not limited to, the following: (1) mechanical capture, (2) plasma spray deposition, (3) dipping/sintering, (4) electrophoretic deposition, (5) porcelainizing, and (6) sputtering.

1.4 Substrates may include smooth, porous, textured, and other implantable topographical forms.

1.5 This specification excludes organic coatings that may contain calcium and phosphate ionic species.

2. Referenced Documents

2.1 ASTM Standards:

E 376 Practice for Measuring Coating Thickness by Magnetic-Field or Eddy-Current (Electromagnetic) Test Methods⁴

F 1044 Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings⁵

F 1088 Specification for Beta-Tricalcium Phosphate for Surgical Implantation⁵

F 1147 Test Method for Tension Testing of Calcium Phos-

phate Coatings and Metallic Coatings⁵

F 1160 Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallis Medical and Composite Calcium Phosphate Metallic Coatings⁵

F 1185 Specification for Composition of Ceramic Hydroxylapatite for Surgical Implants⁵

F 1854 Shear and Bending Fatigue Testing of Calcium Phosphate and Metallis Medical and Composite Calcium Phosphate Metallic Coatings⁵

F 1926 Test Method for Evaluation of the Environmental Stability of Calcium Phosphate Coatings⁵

F 2024 Practice for X-Ray Diffraction Determination of Phase Content of Plasma-Sprayed Hydroxylapatite Coatings⁵

2.2 Pharmacopeia Convention Documents:⁶

National Formulary XVI, Tribasic Calcium Phosphate
United States Pharmacopeia:

U.S. Pharmacopeia XXI, Chemical Tests CaP (191), Lead <251>, Mercury <261>, Arsenic <211>, and Heavy Metals <231> Method (1)

2.3 Other Documents:

U.S. Geological Survey Method, Cadmium⁷

U.S. Code of Federal Regulations Title 21 (CFR 21), Part 820—Quality System Regulation⁸

X-Ray Diffraction Analyses³

3. Terminology

3.1 Definitions:

3.1.1 *amorphous calcium phosphate*—a non-crystalline calcium phosphate.

3.1.2 *beta tricalcium phosphate*—a calcium phosphate substance of empirical chemical formula, $\text{Ca}_3(\text{PO}_4)_2$ (see Specification F 1088).

3.1.3 *calcium phosphate*—any one of a number of inorganic chemical compounds containing calcium and phosphate ions as its principal constituents.

¹ This specification is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.13 on Ceramic Materials.

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² The boldface numbers in parentheses refer to the list of references at the end of this specification.

³ The Joint Committee on Powdered Diffraction has established a Powder Diffraction File. The committee operates on an international basis and cooperates closely with the Data Commission of the International Union of Crystallinity and ASTM. Hydroxylapatite data can be found on file card No. 9-432; beta tricalcium phosphate data can be found on file card No. 9-169.

⁴ *Annual Book of ASTM Standards*, Vol 03.03.

⁵ *Annual Book of ASTM Standards*, Vol 13.01.

⁶ Available from U.S. Pharmacopeia Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

⁷ Crock, J. G., Felichte, F. E., and Briggs, P. H., "Determination of Elements in National Bureau of Standards Geological Reference Materials SRM 278 Obsidian and SRM 688 Basalt by Inductively Coupled Argon Plasma—Atomic Emission Spectrometry," *Geostandards Newsletter*, Vol 7, 1983, pp. 335–340.

⁸ Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5098, Attn: NPODS.